SUPPORTING STATEMENT

Regulations Under the Federal Import Milk Act (21 CFR Part 1210)

{formerly the Federal Import Milk Act}

OMB No. 0910-0212 - Extension

A. JUSTIFICATION

1 Circumstances Necessitating the Information Collection

All milk and cream imported into the fifty States and the District of Columbia are subject to the requirements of the Federal Import Milk Act (FIMA) of 1927 (21 U.S.C. 141-149) (Attachment A). This Act was passed by Congress "to regulate the importation of milk and cream into the United States for the purposed of promoting the dairy industry of the United States and protecting the public health."

Under the regulations implementing the Federal Import Milk Act, milk or cream may be imported into the United States only by the holder of a valid import milk permit (Attachment B). Before such permit is issued: (1) cows must be physically examined and found healthy, (2) if the milk or cream is imported raw, all cows must pass the tuberculin test, (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements, (4) bacterial counts of the milk at the time of importation must not exceed specified limits, and (5) the temperature of the milk or cream at time of importation must not exceed 50 degrees F. In addition, the regulations require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

We are requesting OMB approval for the following reporting and recordkeeping requirements contained in the following citations which are needed to assure the conformance with the Federal Import Milk Act:

21 CFR 1210.11 - Reporting - Sanitary Inspection of Dairy Farms

Requires reports on the sanitary conditions of dairy farms producing milk and/or cream to be shipped to the U.S. to determine the sanitary conditions of the facility, equipment and processing/milking procedures.

21 CFR 1210.12 - Reporting - Physical Examination of Cows

Requires reports on physical examination of herds producing milk/cream to be shipped into the

U.S. to aid in determining whether or not such herds are in a healthy condition.

21 CFR 1210.13 - Reporting - Tuberculin Tests of Cattle

Requires the reporting of tuberculin testing of all herds producing milk/cream to be shipped into the U.S. to aid in determining whether or not the herds are free of tuberculosis.

21 CFR 1210.14 - Reporting - Sanitary Inspection of Plants

Requires the reporting on the sanitary conditions of plants handling milk/cream to be shipped into the U.S. to determine the sanitary condition of such plants and of their facility, equipment and procedures.

21 CFR 1210.20 - Reporting - Application for Permit

An application for a permit to ship or transport milk or cream into the United States shall be made by the actual shipper on forms prescribed by the Secretary.

21 CFR 1210.22 - Disclosure - Form of Tag

Requires that each container of milk or cream shipped or transported into the United States be tagged with the permit number, type of product, and shipper's name and address. **(Language approval only)**

21 CFR 1210.23 - Reporting - Permits Granted on Certificates

Permits a statement signed by an accredited official saying that copies of reports attached are based on the necessary inspections and examination performed under the supervision of that official.

21 CFR 1210.15 - Recordkeeping - Pasteurization, Equipment/Methods

Requires pasteurization of milk products at proper time and temperature using proper equipment. Requires recordkeeping to include pasteurization/processing charts properly recorded, initialed, numbered, and dated by authorized official and the charts retained for two years.

We are also requesting OMB approval for the following forms which are used in collecting the information (Attachment C):

Form FD-1815 - Certificate/Transmittal for an Application (21 CFR 1210.23)
Form FD-1993 - Application for Permit to Ship or Transport Milk and /or Cream into the U.S. (21 CFR 1210.20)
Form FD-1994 - Report of Tuberculin Tests of Cattle (21 CFR 1210.13)

Form FD-1995 - Report of Physical Examination of Cows (21 CFR 1210.12)
Form FD-1996 - Dairy Farm Sanitary Report (21 CFR 1210.11)
Form FD-1997 - Score Card for Sanitary Inspection of Milk Plants (21 CFR 1210.14)

2. **How, By whom, and for What Purpose the Information is Used**

The information would be used by the Food and Drug Administration (FDA) to determine whether a permit to import milk and/or cream into the United States should be granted.

3. **Consideration of Information Technology**

The major portion of the annual burden for this information collection is associated with FDA form 1996, Dairy Farm Sanitary Report. This form is completed by a sanitarian on-site in rural areas. Under these circumstances, electronic data entry would most likely increase the burden rather than reduce the burden.

4. **Identification of Duplication and Similar Information Already Available**

The information collected in fulfilling the statutory requirements for applying for a permit to import under the FIMA is unique to the dairy herds which are the source of the milk and the plants in which the product is pasteurized.

5. **Impact on Small Business**

Small firms may also apply for a permit. The forms to be completed are simple, consisting of check boxes and short narrative responses. FDA will assist small firms with these requirements thus minimizing the burden.

6. **Consequences of Less Frequent Information Collection**

Submission of the required information and approval of the information after review by FDA is a condition precedent to the issuance of a permit. If the information collection is not conducted, the conditions for the issuance of a permit are not in compliance and no permit can be issued. Since FIMA requires that party importing milk and/or cream into the United States have a valid permit, the ultimate effect would be that the milk and/or cream would be denied entry into the United States.

7. **Explain Any Special Circumstances to the Information Collection**

None of the requirements are inconsistent with the guidelines in 5 CFR 1320.5.

8. **Outside Consultation and Results from the 60-day Comment Period**

On April 30, 1999 (64 FR 23333), FDA published a 60-day notice in the Federal Register soliciting public comment as required under the PRA of 1995 (Attachment D). FDA did not receive any comments regarding the information collection requirements contained in this submission.

We consult from time to time with the New Zealand Embassy and various New Zealand officials regarding the requirements of the Import Milk Act and its regulations. Our contacts in the United States are:

Mr. David Cunliffe, Second Secretary
Embassy of New Zealand
37 Observatory Circle, N.W.
Washington, DC 20008
202-328-4800

and as agent for the New Zealand Dairy Board:

Edward J. Farrell, Esq.
Wigman, Cohen, Leitner & Myers, P.C.
Suite 200
1735 Jefferson Davis Highway
Arlington, VA 22202

Recent inquiries and responses to request for permits under the Federal Import Milk Act have been received from the New Brunswick Milk Marketing Board, Sussex, New Brunswick, Canada and Nelson Dairy, Halton Hills, Ontario, Canada

9. **Payment to Respondents**

This information collection does not provide for payment or gifts to respondents.

10. **Confidentiality of Information**

The information and data collected do not concern any method or processing which is entitled to protection as a trade secret nor is it concerned with matters that are commonly considered private or sensitive in nature. No assurance of confidentiality is given.

11. **Sensitive Questions**

This information collection does not involve any questions of a sensitive nature.

12. **Burden Hour Estimates**

The burden to respondent in requesting an Import Milk Permit is estimated on the basis of this information being collected as part of a foreign State's regular control activities. But, in assessing the burden involved by the United States requirements, it is estimated that the time required to respond to our reporting and recordkeeping requirements is approximately 1212 hours annually.

The information is collected and reported to FDA by the respondent is provided on six (6) different established forms which are listed individually below with estimated completion time on each form. It is estimated that the four (4) respondents will submit approximately 200 FD-1996 report forms annually.

All dairy plants are required under the Import Milk Act to have pasteurizing machinery with accurate time and temperature recording devices. These devices automatically produce thermograph charts which are initialed, numbered, and dated by an official of the plant. Plant officials estimated an annual recordkeeping burden of approximately .05 hours per report, or a total recordkeeping burden of .05 hours x 1 report (FD 1997) = .05 hours. These estimates have been made by persons in the program area who have specific knowledge and experience in this particular field.

FDA estimates the burden of complying with the information collection provisions of these regulations as follows:

Estimated Annual Reporting Burden						
Form No.	CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	4	1	4	0.5	2.0
FDA 1993/Application of permit	1210.20	4	1	4	0.5	2.0
FDA 1994/Tuberculin test	1210.13	0	0	0	N/A	0
FDA 1995/Physical examination of cows	1210.12	0	0	0	N/A	0
FDA 1996/Sanitary inspection of dairy farms	1210.11	4	200	800	1.5	1200

Estimated Annual Reporting Burden						
FDA 1997/Sanitary inspections of plants	1210.14	4	1	4	2 .0	8.0
Totals						1212.0

Estimated Annual Recordkeeping Burden					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 1210.15	4	1	1	.05	0.20

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

No burden has been estimated for Forms FD 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FD 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FD 1994 and 1995. To date, Form FD-1815 has been submitted in lieu of these forms.

The annualized cost for the burden hours is estimated at $18,180. This is based on a cost of $15/ man-hour x 1212 total burden hours = $18,180.

13. **Total Annual Cost Burden to Respondents**

There are no capital costs nor operation and maintenance costs associated with this collection. Many of the requirements are also regulatory requirements of the foreign government to which these establishments belong. By complying with their own regulations they also comply with many of ours, mitigating the cost burden. This particularly applies to tuberculosis testing and physical examination of herds, which are required by the government of New Zealand.

14. **Annualized Cost to the Federal Government**

The total annual cost to the Federal Government is $2,786. FDA estimates that the staffing burden currently assigned to review and respond to the current level of applications for a permit to import milk and/or cream to this country is 10 man-hours or 80 hours at a GS-13 level (80 hours x $31.62man-hour = $2,530). Additional reviews at the Division, office/center and Associate Commissioner levels are estimated by program specialists to take an additional 8 man-hours at an aggregate rate of $32/hour equally $256 total or (8 man-hours x $32/hour = $256).

15. **Explanation of Change in Items 13 and 14**

This increase in the annual burden is due to three additional applicants requests for a permit to export milk and/or cream to this country

16. **Statistical Reporting**

No comprehensive tabulation of the data is planned.

17. **Display of Expiration Date on the Information Collection**

No approval requested.

18. **Exception to Certification Statement**

No exceptions requested.

B. **Collections of Information Employing Statistical Methods**

This collection of information does not employ statistical methods.